

COMMISSIONER FOR PATENT UNITED STATES PATENT AND TRADEMARK OFFIC WASHINGTON, D.C. 20231

MAR 1 3 2003

David J. Josephic Wood, Herron & Evans, L.L.P. 2700 Carew Tower Cincinnati OH 45202-2917

Re: Patent Term Extension Application for

U.S. Patent No. 4,490,351

Dear Mr. Josephic:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,490,351 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

David T. Read cc:

Acting Director Health Assessment Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852

RE: VITREON®

FDA Docket No.: 98E-0849

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Vitrophage, Inc.
Request for Patent Term Extension
U.S. Patent No. 4,490,351

ORDER GRANTING INTERIM EXTENSION

Vitrophage, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,490,351, filed an application under 35 U.S.C. § 156(d)(1), requesting an extension of five years. The original expiration date of the patent was March 15, 2002, and an interim extension of one year has previously been granted pursuant to 35 U.S.C. 156(e)(2), extending the patent to March 15, 2003. The patent claims a method of use of the approved device, perfluorophenanthrene ("VITREON®"). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product. The term of the patent, as previously extended, expires on March 15, 2003.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, a second interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,490,351 is granted for a period of one year from the extended expiration date of the patent, i.e., until March 15, 2004.

MAR 1 1 2003

Date

JAMES E. ROGAN

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office